K014153

MAR 1 5 2002

510(K) SUMMARY

1. SUBMITTER:

Coapt Systems, Inc
261 Hamilton Avenue Suite 413
Palo Alto, CA 94301
Telephone: 650-289-1010

Contact: Jude Paganelli, Vice President Operations
Date Prepared: December 10, 2001

2. DEVICE:

Endotine Device
Classification Name: Bioabsorbable Fixation Device
Trade Name: Coapt Systems Endotine Device

3. PREDICATE DEVICE:

The predicate device used to determine substantial equivalence for the Endotine Device was the Bionx Endobrow Screw marketed by Bionx Implants, Blue Bell, PA

4. DEVICE DESCRIPTION:

The Endotine Device is a device fabricated from L-PLA that is intended for use in browplasty procedures. The device is molded with a post that is inserted directly into the cranial bone. A series of barbs along its face provides a feature that allows for the direct fixation the sub-dermis without the use of suture. The device is inserted into the bone with the use of an installation instrument. Additional instruments include a stepped drill and sterilization tray.

5. INTENDED USE:

The Endotine Device is intended for use in browplasty surgery. The Endotine device is specifically intended for use to fixate the sub-dermis to the cranial bone in browplasty procedures.

6. COMPARISON OF CHARACTERISTICS:

The Endotine Device is fabricated from L-PLA, while the Bionx Endobrow Screw is fabricated from L/DL-PLA. The Endotine device design provides direct fixation to the sub-dermis. The Bionx Endobrow Screw provides fixation to the device through the use of suture that is affixed to the sub-dermis.

The indications for use of the two devices are identical.

7. PERFORMANCE DATA:

The following performance data was provided in support of the substantial equivalence determination:

1. Bench Testing: Comparison of the shear strength of the Endotine Device In-Vitro compared to the predicate device.
2. Animal Testing: The testing demonstrated the acceptability of the Endotine Device and confirmed that the device functions adequately to meet its intended use.
3. Tissue Interface: Comparison of the device to tissue interface of the Endotine Device to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2002

Ms. Jude Paganelli
Coapt Systems Inc.
261 Hamilton Avenue
Suite 413
Palo Alto, CA 94301

Re: K014153
Trade/Device Name: Endotine Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: December 10, 2001
Received: December 18, 2001

Dear Ms. Paganelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

The Endotine Device is intended for use in browplasty surgery. The Endotine device is specifically intended for use to fixate the sub-dermis to the cranial bone in browplasty procedures.

for Mark N Milhouse

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014153